REMARKS

This responds to the Final Office Action dated September 17, 2008 and the Advisory Action dated December 2, 2008.

Claim 1 is amended, and claims 82-84 are added. Claims 1-10, 12-14, 73-79, and 81-84 are pending in this application.

§103 Rejection of the Claims

Claims 1-10, 12-14, 73-79, and 81 were rejected under 35 U.S.C. §103(a) as being unpatentable over Dennis et al. (U.S. Patent No. 6,114,164, hereinafter "Dennis") in view of Kofidis et al. (Journal of Thoracic and Cardio. Surg., hereinafter "Kofidis"), Farb et al. (U.S. Patent No. 6,048,722, hereinafter "Farb"), Bursac et al. (Am. J. Physiol. 277, hereinafter "Bursac") and Terracio et al. (In Vitro Cell. And Develop Bio., hereinafter "Terracio").

Claim 1

Claim 1 has been amended to better describe the recited subject matter.

Applicant respectfully traverses the rejection and submits that the Office Action does not set forth a proper *prima facie* case of obviousness because the cited portions of Dennis, Kofidis, Farb, Bursac, and Terracio, individually or in combination with each other and reasoning given in the Office Action, do not provide the claimed subject matter. For example, Applicant is unable to find in the cited portions of Dennis, Kofidis, Farb, Bursac, and Terracio, individually or in combination, among other things, one or more biological stimulus agents selected from protein and nucleic acid, and a biological treatment administration module including the one or more biological stimulus agents, as recited in claim 1. Applicant is unable to find in the Office Action a proper reason that remedies this deficiency of the cited references.

The Office Action cites *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969), as cited in MPEP 2115, to support an assertion that "positive recitation in the claims that the apparatus includes a protein or nucleic acid agent does not further patentably distinguish the structure of the claim". However, MPEP 2115 states "that this line of cases is limited to claims directed to machinery which works upon an article or material in its intended use." The biological treatment

administration module does not work upon the one or more biological stimulus agents selected from protein and nucleic acid as recited in claim 1. Therefore, it is believed that *Ex parte Thibault* and MPEP 2115 do not apply.

The Advisory Action asserts:

> It is fundamental that an apparatus claim defines the structure of the invention and not how the structure is used in a process, or what materials the structure houses in carrying out the process. (Citations omitted.) As long as the apparatus of combination of the references recited in the rejection is capable of administering a biological stimulus agent, the prior art device meets the requirements of the claimed feature. Applicant has not established on this record any structural distinction between apparatus within the scope of the instant claim and the device encompassed by the combination of the references set forth in the prior art rejection of record.

Claim 1 has been amended to further clarify that the one or more biological stimulus agents are recited as a structural limitation, rather than what the recited biological treatment administration module is "adapted to include" or "capable of holding". Claim 1 differs from the combination of the cited references in that the claimed biological treatment administration module includes, as part of the structure, the one or more biological stimulus agents selected from protein and nucleic acid.

Applicant also respectfully submits that the Office Action has not provided a properly articulated reason for combining Dennis, Kofidis, Farb, Bursac, and Terracio. The devices in Dennis and Terracio are to mimic *in vivo* mechanical and electrical, or mechanical, respectively, stimuli for *in vitro* analyses of certain cell types. The devices in Farb and Bursac are to measure *in vitro* electrophysiological responses of cells such as microeletrode impaled or cannula ruptured oocytes or rat ventricular cells and cardiac myocytes after perfusion of agents to study membrane physiology or after electrical stimulation for *in vitro* impulse propagation studies, respectively. In Kofidis, calcium and epinephrine, as well as electrical stimulation or stretching, are applied to collagen matrices with spontaneously beating cardiomyocytes, to enhance force development. As each device in Dennis, Kofidis, Farb, Bursac, and Terracio is designed for a particular purpose, there is no proper reason for combining Dennis, Kofidis, Farb, Bursac, and Terracio to arrive at a device to prepare cells for *in vivo* administration and long term maintenance by stimulating cells *ex vivo* prior to cell therapy with a cardiac electrical stimulator, a myocardial stress simulator, and a biological stimulus that enhances one or more of

engraftment, survival, and differentiation of the cells, wherein the biological stimulus agent is a protein or nucleic acid.

In the Advisory Action, it is stated that:

> As long as the apparatus of combination of the references recited in the rejection is capable of administering a biological stimulus agent, the prior art device meets the requirements of the claims feature.

Only Kofidis and Farb disclose adding a chemical agent to cells. Kofidis mounted strips of collagen cultured with cardiomyocytes to the side of a chamber that was filled with culture medium, and calcium and epinephrine were added to the culture medium. Thus, the device of Kofidis apparently does not include a biological treatment administration module coupled to a culturing module. Farb disclose a series of receptacles for chemical agents for delivery to a cell linked to impaling electrodes or delivery via a membrane piercing cannula. Therefore, the device of Farb, while capable of delivering a biological stimulus agent, does not provide an environment that produces cells with long term viability, e.g., those for cell therapy, as the cells are either impaled with microelectrodes or with a cannula that introduces agents into the cytoplasm.

Additionally, Applicant respectfully submits that the Office Action has not provided a rationale for which one of ordinary skill in the art would have had reasonable expectation of success in the combination of the cited references. For example, Applicant is unable to find in the cited references and the Office Action a reason for expecting the delivery of the electrical stimuli, the mechanical stimuli, and the biological stimuli to produce an additional benefit relative to the delivery of a subset thereof. Applicant respectfully requests such a rationale, or withdrawal of the rejection.

Applicant respectfully requests reconsideration and allowance of claim 1.

Claims 2-10, 12-14, 73-79, and 81

Applicant respectfully traverses the rejection. Claims 2-10, 12-14, 73-79, and 81 are dependent on claim 1, which is believed to be patentable for at least the reasons set forth above. Therefore, the discussion above for claim 1 is incorporated herein to support the patentability of claims 2-10, 12-14, 73-79, and 81.

Applicant respectfully requests reconsideration and allowance of claims 2-10, 12-14, 73-79, and 81.

New Claims

New claims 82-84 have been added. Applicant believes that the new claims are appropriate for consideration in this application and that no new matter is added.

Applicant respectfully requests reconsideration and allowance of claims 82-84.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 373-6965 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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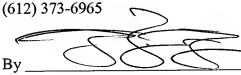
Date February 17, 2009

By 
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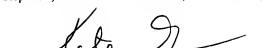
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